

Rapid Diagnostic Testing

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Disclaimer

The views expressed in this presentation are those of the speaker and do not reflect the official policy of the Department of Army, Department of Defense, or U.S. Government



Binax

Now rapid malarial test instructional video:

<http://www.youtube.com/watch?v=bhsXZXqAw7C>

Malaria

- There are several RDTs in the world for malaria testing
- *Binax Now* is the one you will see in DoD (FDA-approved)
 - Takes ~15 minutes to complete
 - Don't need a microscope for this test
 - Single reagent used
 - Very easy to use with minimal training needed
 - Will handle austere environments
 - Reliability:
 - False negatives possible due to:
 - Prozone effect, i.e. lots of parasites, and thus too much antigen available
 - Very early disease with low parasitemia



Parasite Growth in the Blood

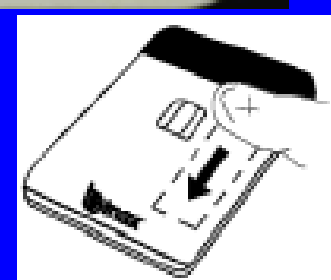
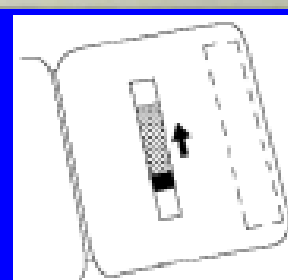
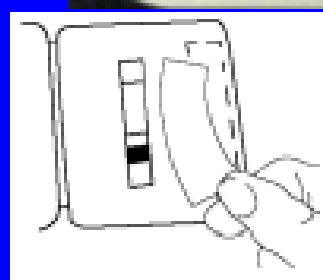
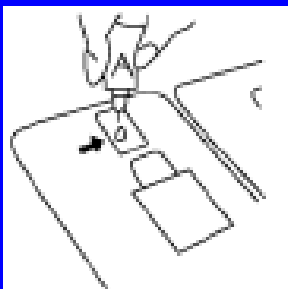
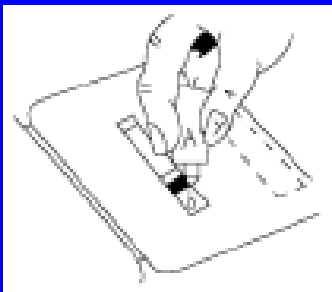
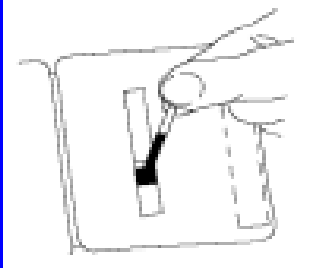
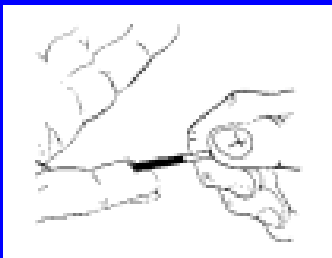
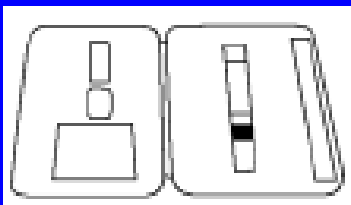
Log+ increase in parasites per 48-hour cycle (for *P. falciparum*)

Threshold	Parasitemia	Parasites/ml	Parasite burden
Expert Microscopy	0.0005%	20-50/ml	10^8 parasites
Symptoms in non-immunes	0.002%	100/ml	10^9 parasites
Malaria RDT	0.005%	100-1000/ml	10^9 - 10^{10} parasites
Severe malaria	2%	100,000/ml	10^{12} parasites
Death	10%	500,000/ml	10^{13} parasites

Malaria

THIS TEST DOES **NOT** REPLACE
MICROSCOPY AS YOU NEED TO LOOK
AT THE SMEAR TO:

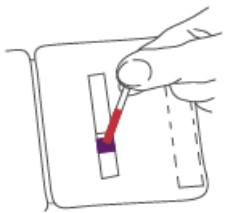
1. Confirm the RDT result
2. Determine the species
3. Determine the % parasitemia
4. Confirm you don't have a false negative



Easy to Use

1

Apply 15 μ L of blood to the bottom half of the purple pad.



2

Apply 2 drops of Reagent to the white pad immediately below where the blood was applied.



3

Apply 4 drops of Reagent to the pad located at the top of the left hand side of the test card.



4

When the blood sample reaches the base of the white absorbent pad at the top of the test strip, close device and read at 15 minutes.



Malaria

- There are 3 bands or lines:
 - C = control band
 - T1= *Plasmodium falciparum* (i.e. the “bad” malaria)
 - Histidine Rich Protein 2 (HRP2) antigen
 - T2= All malaria species (panmalarial aldolase)

Malaria

- Interpretation:
 - All 3 bands positive either:
 - *P. falciparum* or
 - Mixed infection (i.e. *P. falciparum* plus another species)
- C and T1 positive: *P. falciparum*
- C and T2 positive: *P. vivax*, *P. ovale*, *P. malariae*
- C only positive: NEGATIVE

Malaria

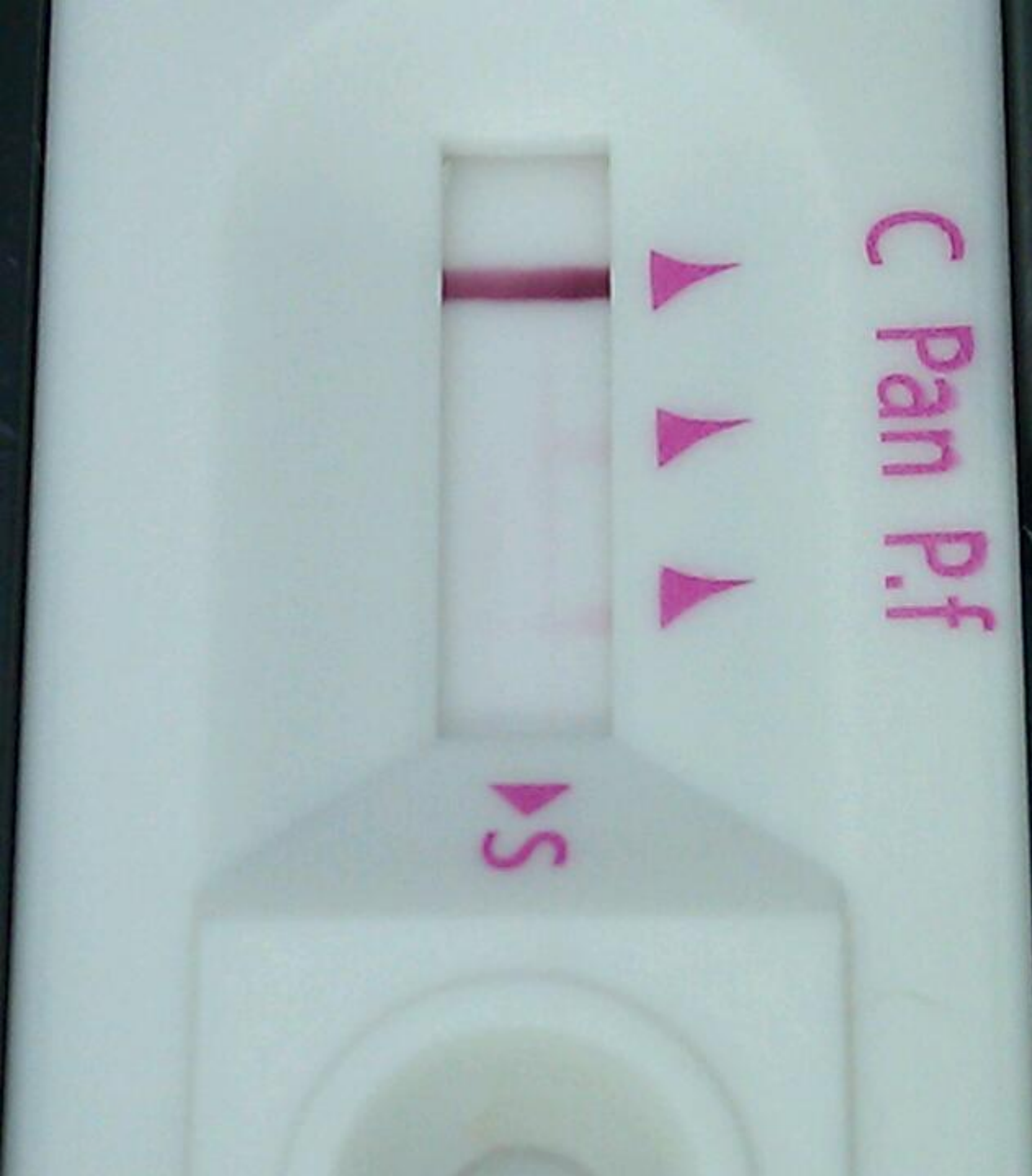
- Binax NOW Malaria

Sensitivity		Specificity	
<i>P. falciparum</i>	99.7%	94.2%	
<i>P. Vivax</i>		93.5%	99.8%

- **THESE SENSITIVITY NUMBERS ARE DEPENDENT ON THE PARASITE BURDEN**

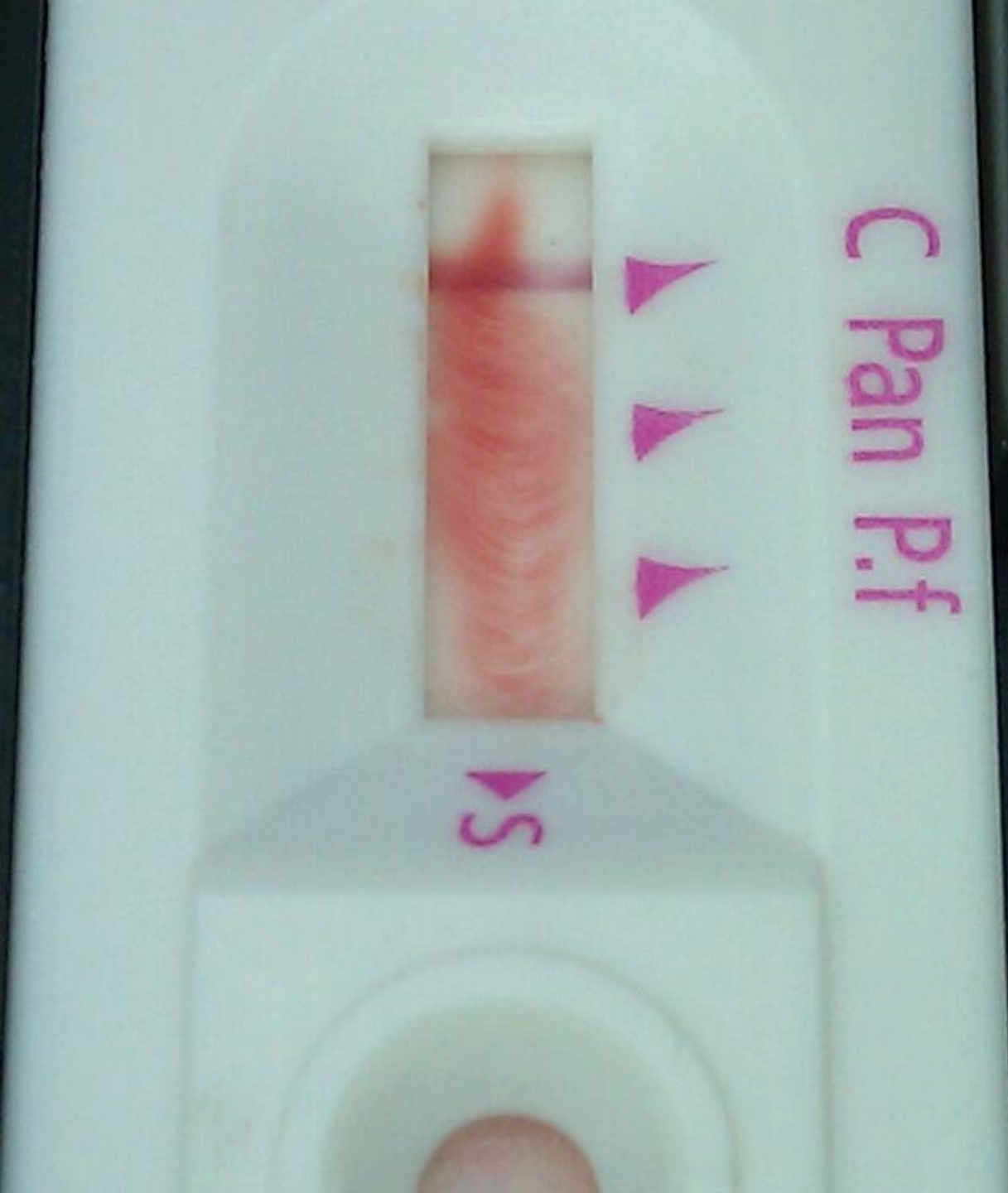
- The lower the parasitemia (early disease) the lower the sensitivity
- *P. ovale* and *P. malariae* sensitivity only ~50%

Missed weak
positive





Need some training as the tech called this “negative” even though the control band didn’t work correctly



Breakdown in
quality control
(reagent
issues?)

HIV

- Typically used for point of care
- Many of the tests now have HIV-1 and 2 capability
- Needs confirmatory testing for positive results
 - Typically have extremely high sensitivity so if NEGATIVE the patient is nearly guaranteed to be HIV negative
 - If you suspect an acute HIV infection, the sensitivity will be much lower (i.e. don't use to screen acute HIV)
- Results are typically available in less than 30

HIV

- RDTs available:
 - OraQuick Advanced Rapid HIV 1/2 Ab test
 - OraSure HIV-1 Western Blot test
 - Uni-gold Recombigen HIV-1 test
 - Reveal G-3 Rapid HIV-1 Ab test
 - Multispot HIV -1/HIV-2 Rapid test
 - Clearview HIV-1/2 Stat Pak
 - VITROS Anti HIV 1/2 test

Rapid HIV test*	Specimen type	Sensitivity[†]	Specificity[†]	CLIA category
OraQuick® Advance Rapid HIV-1/2 Antibody test	Oral fluid	99.3% (98.4–99.7)	99.8% (99.6–99.9)	Waived
	Whole blood (fingerstick or venipuncture)	99.6% (98.5–99.9)	100% (99.7–100)	Waived
	Plasma	99.6% (98.9–99.8)	99.9% (99.6–99.9)	Moderate complexity
Reveal™ G-2 Rapid HIV-1 Antibody test	Serum	99.8% (99.5–100)	99.1% (98.8–99.4)	Moderate complexity
	Plasma	99.8% (99.5–100)	98.6% (98.4–98.8)	Moderate complexity
Uni-Gold Recombigen® HIV test	Whole blood (fingerstick or venipuncture)	100% (99.5–100)	99.7% (99.0–100)	Waived
	Serum and plasma	100% (99.5–100)	99.8% (99.3–100)	Moderate complexity
Multispot HIV-1/HIV-2 Rapid test	Serum	100% (99.94–100)	99.93% (99.79–100)	Moderate complexity
	Plasma	100% (99.94–100)	99.91% (99.77–100)	Moderate complexity

*Trade names are for identification purposes only and do not imply endorsement by the US Department of Health and Human Services or the Centers for Disease Control and Prevention.


- The OraQuik and Uni-Gold products can be stored at room temperature
 - The other two need their reagents refrigerated

OraQuick

positive result



Any line



even a faint line



In home
testing
capability

OraQuick instructional video:

[http://
www.youtube.com/watch?v=5FBWORY91J4](http://www.youtube.com/watch?v=5FBWORY91J4)

Uni-Gold™

HIV

Control

Test

Sample

**TRINITY
BIOTECH**

The background is a deep blue with a subtle grid of fine white lines. A series of wavy, darker blue lines sweep across the top of the image, creating a sense of motion and depth.

Questions?